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EXAMINER

BRUTUS, JOEL F

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afanassieva (Pub. No.: US 2001/0048077) in view of Eguchi et al (US Pat: 4,922,104).

Regarding claims 1, and 3-5, Afanassieva teaches methods of employing fiber optic and spectroscopy using fiber optic sensors operated in the attenuated total reflection regime in middle infrared region of the spectrum of wave numbers between (800 to 4000 cm^{-1}) [see abstract]. Afanassieva teaches apparatus and method that are used to diagnose skin tissue malignancy and pathological tissue or normal tissue in vivo, in vitro and ex vitro that is pertinent to the claimed invention. Afanassieva further teaches diagnostics of tissue in vivo, optical spectroscopy, Fourier transform techniques in combination with fiber optics and sensors. Tissue measurements are performed in the middle infrared and a fiber optic probe that is in direct contact with the tissue [see 0045, fig 1]. The optical scheme consists of spectrometer, light from IR source passes through an interferometer and focused into optical fibers and fiber probe to input and

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output infrared radiation via focusing lenses [see 0046]; reflected light that is collected from tissue fiber interface onto a detector that is preferably a nitrogen-cooled MCT detector, signal is processed in a microprocessor or computer system [see 0047 and fig 3]. Probe is suitable for detection of normal and malignant tissue with size of 1 mm or less [see 0048].

Afanassieva teaches that the invention can for breast, kidney, stomach, lung, glands and prostate cancer diagnostics [see 0049]; spectrum measured with a resolution of 4 cm^{-1} [see 0049 and 0055]. The invention provides information such as absorbance measured as a peak position, peak height, peak height ratio, peak area, peak area ratio from obtained FTIR tissue spectra [see 0010]; apparatus with several fiber optical probes and accessories for obtaining response data [see 0011]. Fig 7 FTIR spectra of normal skin tissue in vivo, three different bands and fig 8 indicates spectra arising from pigment nevus for three different patients [see 0056]; peak positions in the spectrum is a clear indication of an early stage of cancer [see 0056]. Fig 6 A shows point that is the center of tumor or cancer compared to other points correspond to measurements taken in the direction of normal skin [see 0055]; distances between band position can be used as a parameter for cancer diagnostics [see 0059]; wave number range of $800\text{--}3700\text{ cm}^{-1}$; $800\text{ to }1500$, $1500\text{--}1800$, $2700\text{--}3100$ [see 0017].

Afanassieva teaches probes preferably silver halide fibers can be bent to form an angle creating different probe tips depending on the size of the tissue; MIR fiber tip probe covering a larger tissue segment; forming a tip probe for detection of smaller areas of tissue and this probe is suitable for detection of normal and malignant tissues

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[see 0048]. A needle tip touches a tissue surface and the probe can be used in minimally invasive diagnostics like breast cancer [see 0048]; endoscope or catheter with additional fiber optic cable [see 0049]. The tips of the probe can be changeable for use in biopsy and endoscopic applications; specialized tip size and configuration that allow the collection or scattering of IR light for different type of tissue examinations [see 0049]. IR spectra in the wave number ranges of 800 to 1500 cm^{-1} , 1500 to 1900 cm^{-1} , 2700 cm^{-1} to 3700 cm^{-1} and the ranges can be extended to near and far infrared [see 0051]. Means for comparing band structure, peak positions, peak ratios etc. including visual display of the spectra to be compared. Means for comparing can be superimposed, calculating difference between spectra and subtracting one spectrum from another spectrum in order to reveal differences [see 0057]; comparing normal and premelanoma tissues [see 0058] and microcomputer or computer system [see 0047]. Optical fiber and fiber probe to input and output the infrared radiation via focusing lens or spherical mirrors, probe has direct contact with tissue [see 0046].

Afanassieva doesn't teach two pieces of parabolic mirrors, fine tuning mechanism, and 3-D tuning holder.

However, Eguchi et al teaches a Fourier transform infrared spectrometer, flat mirror, parabolic mirrors to converge parallel lights [see column 5 lines 40-60], optical means for converging, analyzing rays into sample; adjusting position of converging mirror [see column 6 lines 52-55]; adjusting optical system to the position producing correct focal length [see column 7 lines 65-68]; maximizing the intensity of infrared light received by infrared detector with up down drive unit [see column 10 lines 37-43].

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Applicant describes 3 dimensional tuning holder servers to adjust infrared light into detector, fine tuning mechanism to adjust parabolic mirror and abaxial parabolic mirror to converge parallel light onto detector [see specification 0022, 00119].

Therefore one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references; for the purpose of providing evaluation of malignancy with higher precision and greater precision; providing a more pronounced tissue spectrum; using two abaxial mirrors in order to accurately directing light onto appropriate.

3. Claims 6-8, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afanassieva (Pub. No.: US 2001/0048077 A1) in view of Eguchi et al (US Pat: 4,922,104) as applied to claim 1 above and further in view of Stapleton et al (US Pat: 5,803,082).

Regarding claims 6-8, and 14-17, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach mammary glands, cleaning and sterilizing the ATR probe and the skin.

However, Stapleton teaches detecting cancer using mammary duct, glandular tissues [see column 17 lines 41-46].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by detecting cancer using mammary duct and glandular tissues; for the purpose of providing a reliable diagnostic

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of breast cancer/tumors. An artisan would be motivated to use these specific wave numbers because the right wave numbers for tissues, glands etc... One with ordinary skill in the art at the time the invention was made would be motivated to clean and sterilize the ATR probe and the skin for optimizing signal resolution.

4. Claims 2, 9-13 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afanassieva (Pub. No.: US 2001/0048077) in view of Eguchi et al (US Pat: 4,922,104) as applied to claim 1 above and further in view of Dukor et al (Pub. No.: US 2002/0164810).

Regarding claims 2, 9-13 and 18-22, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach thyroid, submaxillary, and parotid glands.

However, Dukor et al teaches a method and system for diagnosing pathology in a biological sample [see abstract]. Dukor et al teaches using mid infrared spectrometer in the mid infrared region [see 0015, fig 2, 0016, fig 3, 0017]. Dukor further teaches the invention can diagnose thyroid disorders such as hypothyroidism, goiter, and thyroiditis [see 0050]. ZnSe lens which focuses infrared light from sample onto detector [see 0054].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references; for the purpose of diagnosing malignancies in the mouth/throat. One with ordinary skill would be motivated to diagnose in the areas of submaxillary and parotid glands; for the purpose of providing a

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more complete diagnosis of the mouth/throat. An artisan would use ZnSe as a window material because Zinc selenide is essentially free of extrinsic impurity absorptions, providing extremely low bulk losses from scatter. Having a very low absorption of energy makes it useful for optical components in high power laser window and multispectral applications, providing good imaging characteristics. ZnSe is also useful in high resolution thermal imaging systems, where it is used to correct for color distortion which is often inherent in other lenses used in the system.

5. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Afanassieva (Pub. No.: US 2001/0048077 A1) in view of Eguchi et al (US Pat: 4,922,104) as applied to claim 1 above and further in view of Doyle (US Pat: 5,818,996).

Regarding claim 4, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach tapered hollow fibers with metal coating.

Doyle teaches in fig 2 reflected is collected by a hollow metallic light guide into an infrared area detector [see column 2 lines 56-66]. Fiber optic bundles that have a plurality of fibers transmitting and receiving [see column 3 lines 34-37].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references; for the purpose of accessing the region of interest smoothly.

Response to Arguments

6. Applicant's arguments filed 4/21/2009 have been fully considered but they are not persuasive.

Applicant admits that Eguchi discloses the abaxial parabolic mirror and argues that Eguchi doesn't teach two abaxial mirrors.

Examiner disagrees because Applicant describes abaxial parabolic mirror for the use of converging parallel light onto detector [see specification 0022, 00119].

However, Eguchi et al teach flat mirror (10 and 12) for receiving parallel rays and direct them toward a parabolic mirror and the rays are converged by a reflective objective or an ellipsoidal mirror [see column 3 lines 1-35].

Therefore one with ordinary skill in the art at the time the invention was made would have been motivated to use two abaxial mirrors in order to accurately directing light onto a desired region of interest.

Applicant also argues that the database claimed is established with about 20 thousand spectra for many tissues such as mammary glands, parotid glands, thyroid glands, kidney, lung, stomach, liver, womb, skin, gallbladder and finger. This specific limitation is not part of any of the claims. Applicant only claims a database of spectral infrared of spectral data.

Applicant also argues that their invention limits the tip shape of the probe to as tapered or cylindrical. Examiner relies on the teaching below.

Afanassieva teaches probes preferably silver halide fibers can be bent to form an angle creating different probe tips depending on the size of the tissue; MIR fiber tip

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probe covering a larger tissue segment; forming a tip probe for detection of smaller areas of tissue and this probe is suitable for detection of normal and malignant tissues [see 0048]. A needle tip touches a tissue surface and the probe can be used in minimally invasive diagnostics like breast cancer [see 0048]; endoscope or catheter with additional fiber optic cable [see 0049]. The tips of the probe can be changeable for use in biopsy and endoscopic applications; specialized tip size and configuration that allow the collection or scattering of IR light for different type of tissue examinations [see 0049].

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768